ATTORNEY DOCKET NO. 2001180-0077 (HU 2060-02 US NATL) IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Schreiber et al.

Examiner:

Solola, Taofiq A.

Serial No.:

10/649,532

Art Unit:

1639

Filing Date:

August 27, 2003

Title:

DIHYDROPYRANCARBOXAMIDES AND USES THEREOF

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Commissioner for Patents

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Sir:

DECLARATION UNDER 37 C.F.R. 1.131

I, Robert A. Stavenger, Ph.D., declare as follows:

- 1. I am an inventor of the subject matter disclosed and claimed in United States Patent Application Serial No. 10/649,532 ('532 application) filed August 27, 2003, and entitled "DIHYDROPYRANCARBOXAMIDES AND USES THEREOF". This application claims priority to United States provisional patent application Serial No. 60/406,140, filed on August 27, 2002.
- 2. This Declaration is presented for the purpose of removing from consideration by the Examiner the following two papers:
- (i) Clemons et al. "A one-bead, one-stock solution approach to chemical genetics: part 2", Chem. Biol. 8:1183-1195, 2001 (hereinafter, "Clemons"). As indicated on the front page of the paper, the article first published online on November 7, 2001. Thus, the paper first became available to the public on November 7, 2001.
- (ii) Blackwell et al. "Decoding Products of Diversity Pathways from Stock Solutions Derived from Single Polymeric Macrobeads", Angew. Chem. Int. Ed. 40(18):3421-3425, 2001 (hereinafter, "Blackwell"). The paper first became available to the public on September 14, 2001.

Therefore, both the Clemons and Blackwell papers became available to the public less than one year prior to the filing of the provisional application to which the present application claims priority.

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The present Declaration is presented in accordance with <u>In re Stompel</u>, 113 U.S.P.Q. 77 (CCPA 1957) and establishes conception and reduction to practice of the invention in this country before September 14, 2001.

- 3. While the publication date of the edition of Angewandte Chemie International Edition in which Blackwell appeared was September 17, 2001, the article was first published online on September 14, 2001 as indicated in the print out of the Journal's web page (Exhibit 1, page 5).
- 4. The inventors of the claimed subject matter of United States Patent Application Serial No. 10/649,532 are Stuart L. Schreiber, Robert A. Stavenger, Timothy J. Mitchison, and Zoltan Maliga.
- 5. On a date before September 14, 2001, Stuart L. Schreiber, Timothy J. Mitchison, and Zoltan Maliga and I conceived and reduced to practice our invention of dihydropyrancarboxamide compounds and uses thereof.
- 6. Exhibit 2 is a copy of several pages from my laboratory notebook, with dates blacked out. Exhibit 2 provides evidence of conception and actual reduction to practice of the claimed invention prior to September 14, 2001. In particular, pages 17-20, 22-24 and 26-29 include a description of a synthesis of a library of dihydropyrancarboxamide compounds, using vinyl ether, unsaturated ketoester and amine building blocks disclosed in the specification, as filed. For example, page 17 describes vinyl ether building blocks BB1-A through BB1-H depicted on page 61 of the specification. Page 20 describes unsaturated ketoester building blocks BB2-A through BB2-J depicted on page 62 of the specification. Page 26 describes amine building blocks BB3-A through BB3-Y depicted on page 66 of the specification. Finally, pages 31-34 include a description of the decoding process of the dihydropyrancarboxamide library. The notes were prepared in the United States of America.
 - 7. The originals of these documents bear dates prior to September 14, 2001.

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8. All statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful, false statements may jeopardize the validity of the application or any patents issued thereon.

Robert A. Stavenger, Ph.D.

Au 30,2006

Date



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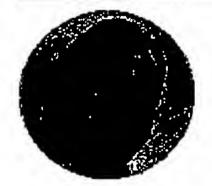
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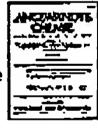
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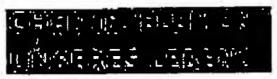
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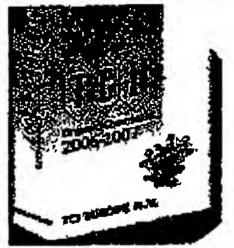
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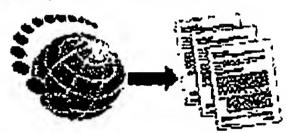
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Hans-Georg Schmidt

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DOI: 10.1002/1521-3773(20010917)40:18<3461::AID-ANIE3461>3.0.CO:2-3

Abstract | References | Full Text: HTML, PDF (Size: 173K)

Save Article

Anion-Templated Syntheses of Rhombohedral Silver-Alkynyl Cage Compounds (p 3464-3467) Daniela Rais, John Yau, D. Michael P. Mingos. Ramon Vilar, Andrew J. P. White, David J. Williams Published Online: 14 Sep 2001

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The Self-Assembly of an Unexpected, Unique Supramolecular Triangle Composed of Rigid

Subunits (p 3467-3469)

Manuela Schweiger, S. Russell Seidel, Atta M. Arif, Peter J. Stang

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Microencapsulated Palladium Catalysts: Allylic Substitution and Suzuki Coupling Using a

Recoverable and Reusable Polymer-Supported Palladium Catalyst (p 3469-3471)

Ryo Akiyama, Shū Kobayashi Published Online: 14 Sep 2001

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3 Save Article

A Light-Harvesting tert-Phosphane Ligand Bearing a Ruthenium(II) Polypyridyl Complex as Substituent (p 3472-3474)

Masahisa Osawa, Mikio Hoshino, Yasuo Wakatsuki

Published Online: 14 Sep 2001

DOI: 10.1002/1521-3773(20010917)40:18<3472::AID-ANIE3472>3.0.CO;2-W

Abstract | References | Full Text: HTML, PDF (Size: 85K)

Save Article

The Hexaphosphapentaprismane P₆C₄tBu₄: A "Jaws-Like" Cage Molecule That Bites! (p 3474-

3477)

Mehmoud M. Al-Ktaifani, Daniel P. Chapman, Matthew D. Francis, Peter B. Hitchcock, John F. Nixon.

László Nyulászi

Published Online: 14 Sep 2001

DOI: 10.1002/1521-3773(20010917)40:18<3474::AID-ANIE3474>3.0.CO;2-K

Abstract | References | Full Text: HTML, PDF (Size: 130K)

Save Article

Book Review

Rutherford - Scientist Supreme. By John Campbell (p 3479)

Günter Herrmann

Published Online: 14 Sep 2001

DOI: 10.1002/1521-3773(20010917)40:18<3479::AID-ANIE3479>3.0.CO;2-R

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Ulrich Panne

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Chiral Catalyst Immobilization and Recycling. By Dirk E. De Vos, Ivo F. J. Vankelecom and Pierre A.

Jacobs (p 3480)

Rainer Haag

Published Online: 14 Sep 2001

DOI: 10.1002/1521-3773(20010917)40:18<3480::AID-ANIE22223480>3.0.CO;2-Q

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Matthias Epple

Published Online: 14 Sep 2001

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Web Site

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Burkhard Kirste

Published Online: 14 Sep 2001

DOI: 10.1002/1521-3773(20010917)40:18<3483::AID-ANIE3483>3.0.CO;2-O

Abstract | Full Text: HTML, PDF (Size: 79K)

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15 pages

		BEST AV	AILABLE	COPY	15 pages	17
-	Marking	the litera	Sty 1	- Londing.		
-	1707	7folf +	Seg.	2014		
Mer	143mi, /5 mx	1 150.07 (1.696	107.18 (0-920	1) sec below		
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	·	stood for	30 min.	Filtered (Ar	PHISMA / -	Cussland
	1 4x3m2 x2	nin CHU)	· Tfoll la	15 -3% 50/	n Ulh	-8-6-6)
•	added - ruin	turnd wens	immodel	1. Question	1/2 md	
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	Virgitated acco		- A 871-2	H0~~	.0. //	C ₆ H ₁₂ O ₂
	for 25 min.	Filtered	- · · · · · · · · · · · · · · · · · · ·		Mol.	C ₆ H ₁₂ O ₂ Wt.: 116.16
	+ washed as		- #0 H	0~0	√ 0∕∕	C ₂ H ₁₄ O ₂ —
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	brokden odde		C 98mg +	40~~	`∩=+	C ₇ H ₁₄ O ₂
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•	then ving to there		D 98m	HO /	J Mai	C ₇ H ₁₄ O ₂ Wt.: 130.18 —
	in feel (HU) 9	41,2	•			- 130.18
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	25 h then w			0/0/	OEI	C ₁₀ H ₂₀ O ₄ — Mol. Wt.: 204.26
	13+5ml + 1 min 6					
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	14 25AL 215m			~ ·0· ~		C ₁₀ H ₂₀ O ₄ — Mol. Wt.; 204,26
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	18-19		H 226mg	O≂S≈O	C	₁₃ H ₁₉ NO ₅ S . Wt.: 301.36
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18		•				•	•
	Maki	of the Lit	each . wh	102- 10	t enco	1,14	
	8 Resin pe	ods for	pp 17	A>	<i>H</i>		
	Scheme >						
		resin pool	TaB (CaCla)	T ₄ B (C ₆ Cl ₃)	T ₁ A (C ₃ Cl ₅)	T ₂ A (C ₄ C(₅)	
		A	X				
		В		Х			
	-	C			X		
		D				X	
		E	X	Х			
		F	X		X		
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		, H		X	X		
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	Procedure	:					•
	each	botch o	1150	placed in	dr	8ml L	ope total
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	1 toru	2) - 195 5	typs LE	FGH)	see u	seights	on best
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(Phoce OJ, R)	(9/0/75	+ Sp/7.	14 nt st	2.50 - ML) aktid	ad sh	gke, 197
	shaken	L/J	then fil	Him 2 an	d was		
		min & Jal	CH, U, 1	45mL 15,	nly tHE.	125mL	voh the
		2 + 10 min					19
	1	•					

		BEST AVA	AILABLE C	OPY	19
(cont.)			-		
·	resin pool	T ₂ B (C ₄ Cl ₃) mw 443.7	T ₄ B (C ₆ Cl ₃) mw 471.75	T ₁ A (C ₃ Cl ₅) mw 498.58	T ₂ A (C ₄ Cl ₅) mw 512.61
·	A	29.7 mg	ø	ø	6
	В	Ø	31.8 mg	Ø	\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\
		ø	ø	33.5 mg	4
	D	Ø	Ø	16	34.5 mg
	E	14.9 mg	15.9 mg	Ø	15 ·
	F	14.9 mg	. 9	16.7 mg	9
	G	14.9 mg	ß	×	17.2 mg
	Н	Ø	15.9 mg	16.7 mg	. 10
			•		
	Risi- pools d 2-12- recin portions cockeadd	+ rolphod ja	divide 1x15 n divide 1 ment page	Lx 30 mg. THE	3 x 15 m L+30-m/n

20	TOTAL COPY
•	Cycloudition.
	Vine 1 than risin 1 (1) + Cu (01/) + 4/ ms
	stock solve totalet - 14/m, blood + A3m, Cy (070). 150my sieurs in 12.8ml THE stored Q ret top 1/h. cerp ques color
each vial =	Redu from 19 (20 vials) added the vials contain, diens 1 (see 60 ment) + 10 mg steres thes put under An
Plin.	+ 800 of do, THE added, followed by 800 of 1-stalyst sola (20 mol 9.). VIIIs shope for 20 h the washed. Yusal x30 air THE, 3 x5 al x ZEEnis CH, Ch.
1100 - 0.45 m	
	24 25 24 25 25 25 26 33 31 326.35
C ₁₀ 81 ₁₄ 0 ₃ Mof. WI.: 182.22 C _{1,3} 11 ₁₂ 0 ₃	C20H16O3 Mo1, WL: 304.34 Mo1, WL: 304.34 C15H4O5 Mo1, WL: 274.27 C15H2O3 Mo1, WL: 222.26 Mo1, WL: 222.26 Mo1, WL: 297.31 C17H18NO4 Mo1, WL: 297.31 C18H18N2O4 Mo1, WL: 397.31 Mo1, WL: 397.31 Mo1, WL: 336.35 Mo1, WL: 326.35 Mo1, WL: 326.35 Mo1, WL: 326.35
>	Mol. Wit. 2 Mol. Wit. 3 Mol. Wit. 4 Mol.
9	O M M O 7 · J

22	-				BEST	AVAILA	BLE COPY
		Making)	the liberty	Step 4	1 - 1999	1	· · · · · · · · · · · · · · · · · · ·
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		1 / Jin 9.	nd tags	Sue MEX	A series	* Mossas	- 16.8 m W Tax Solo Pur 1 to, (20A-20E)
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		for 3 to	15 (g/ [=- 1/17)	g/ <u>=</u>	20 9004	
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		see Filh	Rd + W	wed 2	45mL 41	Smir CH	L1 2 5 ml x 15 mis THE
	· -	1=5-1-6	KJHF.	2x Sal x1	Smin 7H	7x 5	of + 15 min CH, CL
·							
	Resin pool	T3A (CSCI5) mw 526.64	T4A (C6CI5) mw 540.67	T5A (C7CIS) mw 554.70	TBA (CBCIS) mw 568.73	17A (C9CIS) nw 582.76	
	20Å	х					
	20B		X	X			
	20C				X		·
	20D 20E					х	
	20F	<u> </u>	X		_		
	20G	Х	<u></u>	x			
	20H	X			X		
	201	X				X	
	20J		Х	Х			
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(114)	Resin pool	T3A (C5CI5) mw 526.64	T4A (C6CI5) mw 540.67	T5A (C7CI5) mw 554.70	T6A (C8CI5) mw 568.73	T7A (C9CI5) mw 582.76
(coxt)	20A	14.2mg	ø	ø	ø	Ø
	20B	Ø	14.5mg	b	ø	D.
,	20C	6	d	14.9mg	Ø	y
	20D	d	Ø	ø	15.3mg	15
	20E	1/4	4	ø	ø	15.7mg
	20F	7.1mg	7.3mg	ø	ø	d
	20G	7.1mg	8	7.5mg	B	
	20H	7.1mg	6	Ø	7.6mg	<i>B</i> -
•	201	7.1mg	d	Ø	d	7.9mg
	20J	. 0	7.3mg	7.5mg	Ø	15
	21A	8	7.3mg	4	7.6mg	
	21B	8	· 7.3mg	1	6	7.9mg
	21C	6	8	7.5mg	7.6mg	15
	21D	Ø	8	7.5mg	B.	7.9mg _
	21E	. 6	d	6	7.6mg	7.9mg
	21F	4.7mg	4.8mg	5.0mg	Ø · ·	Ø
	21G	4.7mg	4.8mg	Ø	5.1mg	ø.
	21H	4.7mg	4.8mg	Ø	Ø	5.2mg
	21I	4.7mg	8	5.0mg	5.1mg	0
	21J	4.7mg	8	5.0mg	Ø	5.2mg -
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		pool 21	→ 1.4426	5 57/;3	out 149 49	9mg
				ngt stpp	(pp 24)	
	1		1 (c 1	. دخوی مید. م	(pg 24)	

24	
-	Making the library step 5 - Leallylation!
	resin + (Ph. Ph. Pd., Och THE)
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4mul	
my	1.5 1.5 10.5
· · · · · · · · · · · · · · · · · · ·	Both rear pools trested as below.
	11-cat dividue in 16 ml THF Miln added
	followed by thiotodicylic quid + deep sed mixtures Slasken for 12h.
	149Kin +k /2h.
	Filted and washed 4×15mLx14 THE 2 x15mLx DMF
	1 × 15 m/ 15 min THF 1 15 15 min JMF 43 15 min CH, C/
	then dois
	From 20 pool - 1.734
• •	
	from 21 pool - 1.356g:
	Each pool then split into a6 equal partism
	ie 20,001 -> 51.4ms
······································	. and provided to next step
	end provided to next step

26	BEST AVAILABLE COPY
	Making the Library Step 6: amide formation.
- :	acids + grimes + R.BOP + iPr.NEX>
Na	(ver) 520.3 129.25 (0742)
anist	290m, 98.L
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9	1.0
	i 0 40/43 0 -6090
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150mg my	H 107.16Cl 4 107.16Cl 4 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
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	87.12 J NH2 H2N H2N NH2
C Me O	Me Mol. Wt.: 240.32 Mol. Wt.: 241.29 Ö
— HN J	OMe HN F 175-1
D 119.	16 my = 125.75
	160m N 313m, S Pluorobenzylamine 160m Stock Sulns of
methyl cyclohes	triaza Mol. Wt.: 231.29 EMETINE HCL mw 553.58 T
— <u> </u>	307mg (1.50 equel (1.7 mords)
-	136ms 158ms 158ms 100 10
—— Moi. WL: 16 piperidino piper	68.28 heplamethyteneimine
F \	Wt.: 111.18 ketobenzijdazole O2N 255m; TV-40Ch 515- 3-1 U-1.17
	NH2 V NH2 Dale.
2-aminonorbo	NH _z mw=220/1 mw=182.18
Mol. Wt.: 190.24	2HCI, H ₂ O W OMe 105 ms
_ MeO	NH2 151mg H2N
methoxy trypu	HN N-300
	aminoaniline X
	NH ₂ /53m Mol. Wt.: 220.27 O
	1.142.20 NH ₂ 1.3 M ₃
——————————————————————————————————————	pyrrolldinone aminophenol) arninomethylcyclopropane

27

26 -> vi air from "20 pool"
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1600 17, well with in to
To each vial of 18sin , stock solm of CH.C. IP. for wes
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high viewen and kept separated in theles.

icms of library

28

Resin pool	LCMS sample	Resin pool	LCMS sample
26a	1.2	27a	51. 52
26b	3, 4	27b	53, 54
26c	5, 6	27c	55. 56
2 6 d	7.8	27d	57, 58
26e	9, 10	27e	59, 60
26 f	11, 12	27f	61, 62
26g	13. 14	27g	63. 64
26h	15. 16	27h	65, 66
261	17, 18	271	67, 68
26j	19, 20	27j	69, 70
26k	21,22	27k	71.72
261	23,24	271	73.74
26m	25. 26	27m	75, 76
26n	27, 28	27n	77,78
26o	29. 30	270	79, 80
26p	31, 32	27p	81,82
OH	33, 14	279	83.84
26r	35, 36	271	85. 86
26s	37. 38	27s	87, 88
61	39, 40	27t	89, 90
26v	41.42	27u .	91.92
26v	43, 44	27v	93, 94
6w	45, 46	27w	95, 96
бх	47.48	27x	97, 98
бу	49, 50	27у	99, 100
O eycloaddtion	101, 102	2) cycloadditon	103, 104
0 pool (acid)	105, 106	21 pool (acid)	107, 108
 j	/ / /	7.4.4	1 1 1.11
	- 10/1 Deadi	1 701- epper	dorft tusters,
<u> </u>	Mented w/ 1	12.5-1 85/10	15 THF/pp/HF.pgr
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1 50 a to 1	cumpated the s	during ables -	20 of Click and transfered
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29

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Demo cond	dous :	· · · · · · · · · · · · · · · · · · ·	
Beija pool	Mgs I	# of bonds (countred)	
145-1-2929	58.54	339	
741.2-292c	47.2 mg	212	
RAJ-1-1949	48.9mg	304	
RAS-2-294c	37.9mg	250	
R45-2-2979	38.7mg	236	
RAS-2-297c	43.2m	260	

Lemi D.	Ha: Hear pp de. 1st of WR is agak	
7.	\$ (M+1)	
+ml=	Sample # most structure (Lyms) printy	
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<i>a f</i>	· 3 5527 hf	
77	53 35p.0 ba	
	54 512.8 ?	
	5 4/5.9 en fa of carde	
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-J-J	18 4020 61, CB OB	
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	ig 5/4.9 cd dd	_
e	10 500.9 gé, ce, de	
181.87	60 490.9 fgb	
	11 473.9 2/1 eb fb, ac, bd, 99.	-
+	12 479.9 eff	
111.18	6) 614.7 he	
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gains	Sample mass structure
	13 5-928 cafe
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190-27	1 64 573.8 ab
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	16 4979 ah
n	65 452.8 64
147:20	66 5409 cj.d;
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	18 287.0/484.7 MCS!
	67 hp. 0/4847576.7 ga, cb db
186.31	68.674.7 be
	19 640.8
	20 637.7
240.72	69 mess
4701.72	70 529 8 99, cb, db
	21 563.8 aé, ce de
- 4	12 429 8 5128 7.
	71 651.8 Cd fd
73/.77	72 6748, 591.8 ee fe
	27 4928, 407.8 af
	24 617.8
0.02	73 585.8 539.8 ef.f.s
	74 1 5827 ac
	25 4/9.9?
	26 545.8 61.21
201	75 590.8 SW
7147	76 465.8 ge

33

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Anine	sample	mess.	structure		
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